REMARKS

Claims 1-31 are pending in the present application.

At the outset, Applicants wish to thank Examiner Marvich for the indication that the rejection of Claims 1-4, 6-18, 22-25, and 27-21 under 35 U.S.C. §112, first paragraph, and the rejection of Claims 2 and 11-21 under 35 U.S.C. §112, second paragraph, have been withdrawn. Applicants would also like to thank the Examiner for the indication that Claims 6, 7, 9, 22, 23, 27-29, and 31 are free of the art of record.

The rejection of Claims 1-5, 8, 10, 11, 13, 17-19, 24-26, and 30 under 35 U.S.C. §102(e) over Spaulding is traversed.

Spaulding discloses a hydrodynamic cell culture environment for a two-chamber roller bottle (Abstract). Spaulding further discloses that this chamber is made from a broad assortment of organic polymers, such as polystyrene or polycarbonate (column 7, lines 21-31). In Example 8 (column 20, lines 29-56), Spaulding suggests that the roller chamber is useful for fertilizing and developing embryos and co-culturing with endometrial tissue.

However, this disclosure by Spaulding is fundamentally different from the present invention. Present Claim 1 provides: a carrier for co-culturing with a fertilized ovum of an animal comprising a cell incorporated type three-dimensionally reconstructed tissue for co-culturing the fertilized ovum of an animal for the purpose of adhesion and three-dimensional growth of the fertilized ovum, wherein the tissue can substitute a function of endometrial tissue to implant a fertilized ovum and support subsequent growth therefrom.

The Examiner points to the specification at page 9, lines 19-21 and asserts that the cell-incorporated type three-dimensionally reconstructed tissue is any scaffold for growing a

three-dimensional tissue derived from the fertilized ovum. On this interpretation, the Examiner asserts that the roller bottle of Spaulding would qualify as a cell incorporated type three-dimensionally reconstructed tissue for co-culturing. Applicants disagree with this assertion.

In column 2, lines 7-19, Spaulding discuss the features of transplantable tissues and the common problems associated with these tissues. Spaulding focus on the standard tissue culture approaches, which include t-flasks, petri dishes, microgravity culture vessels, roller bottles, and stirred roller bottles. These structures share several traits; perhaps most notably, these structures share the trait of consistently failing to yield transplantable tissue due to the loss of multi-dimensional cell-to-cell contact and overgrowth of unwanted cell populations (column 2, lines 13-19). Another trait shared by these structures is their physical make-up. For example, Spaulding set forth the construction materials at column 7, lines 21-31, which include:

> polystyrene, glass, polyethylene, polysulfone, methyl methacrylate, high density polyethylene, low density polyethylene, polyethylene terephthalate glycol, perfluoroalkoxy, polycarbonate, polyvinylidene fluoride, polytetrafluoroethylene, ultra high molecular weight polyethylene, nylon, Teflon.RTM., crystalline polystyrene, metallocene-based polypropylenes, syndiotatic polystyrene, and the like.

In contrast, the claimed cell incorporated type three-dimensionally reconstructed tissue for co-culturing is a material in which "cells are beforehand incorporated in a culture carrier" to make induction of adhesion and three-dimensional growth possible (page 5, lines 5-10). Applicants submit that with the construction materials of Spaulding, it cannot be reasonably inferred that the cells are "incorporated in" the culture carrier. Applicants have found that it is possible to incorporate the cells into the culture carrier when the carrier contains an extracellular matrix component and/or a mesh network and have clearly

demonstrated the superiority thereof in the Examples. Moreover, Spaulding make no reference to any cellular matrix component and/or a mesh network.

Accordingly, Applicants again submit that Spaulding does not disclose or suggest the use of *a cell incorporated type three-dimensionally reconstructed tissue* as a means for inducing adhesion and three-dimensional growth of a fertilized ovum for co-culturing the fertilized ovum of an animal. The standard for determining anticipation requires that the reference "must teach every element of the claim" (MPEP §2131). Therefore, the absence of any disclosure by Spaulding of a cell incorporated type three-dimensionally reconstructed tissue as a means for inducing adhesion and three-dimensional growth of a fertilized ovum for co-culturing the fertilized ovum of an animal, as defined in the present invention, would necessarily make this reference fail to anticipate the present invention.

In fact, it is *only* the Applicants that have realized the advantages of the present invention and submit that absent the present specification there would be no reason for the artisan to obtain the present inventive co-culturing carrier. Accordingly, Applicants kindly ask the Examiner to not use their disclosure as the guidepost to recreate their invention.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 2 and 11-21 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

This ground of rejection is predicated by the Examiner's inability to interpret how closely related the derived cells, tissues or organs are to the original animals and what procedures were used to derive these cells, tissues or organs, based on the language of the previously pending claims. In order to alleviate this alleged indefiniteness, Applicants have amended Claim 2 to specify that: (a) the cell incorporated type three-dimensionally

reconstructed tissue is tissue/organ engineered and (b) the cells, tissues or organs, are derived from the same animal or a different animal from which the fertilized ovum is obtained.

Regarding point (a), Applicants note that support for tissue/organ engineering is provided by page 10, line 22 to page 11, line 16 and page 14, line 20 to page 24, line 11, which describe several suitable methods that are embrace by this classification. Accordingly, with the present specification in hand, the skilled artisan would recognize that the methods describe in the above-referenced sections embrace tissue/organ engineering. Moreover, the skilled artisan would readily appreciate the scope of this term as used herein.

With respect to point (b), Applicants note that the specification clearly states that the source of the three-dimensionally reconstructed tissue may be from a homogeneous or heterogeneous source. The Examiner is directed to the original specification at page 9, line 22 to page 10, line 16, reproduced (as amended) below:

> The cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are cells derived from an animal that is homogeneous or heterogeneneous to the fertilized ovum as is described in the fourth aspect of the invention.
>
> Further, the cells may be primary cultured cells, strained cells or cells transfected with an exogeneous gene(s). Further, the cells may be one kind or two or more kinds.
>
> In particular, in the case of preparing the cell incorporated type three-dimensionally reconstructed tissue as an implantation model of the fertilized ovum into an endometrium, the cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are preferably cells derived from an endometrium, particularly endometrial epithelial cells and stromal cells as is described in the fifth aspect of the invention.
>
> Similarly, as the cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue, cells derived from an ovary or cells derived from a uterine tube may be used to mimic an in vivo environment of about a life cycle of the ovum to be cultured.

In view of the foregoing, Applicants submit that Claim 2, and Claims 11-21 by dependency, are definite within the meaning of 35 U.S.C. §112, second paragraph.

Applicants respectfully request withdrawal of this ground of rejection.

The objection to the specification is believed to be obviated by submission of the attached substitute specification. Applicants submit that the substitute specification contains no new matter.

Applicants have further amended the specification to address the points that the Examiner has specifically indicated as being unclear. Applicants note that the scope and meaning of the specification is clear and is free of improper idiomatic English. Moreover, with the specification in hand, the skilled artisan would be able to interpret the metes and bound of the claims so as to understand how to avoid infringement (MPEP §2173.02). Accordingly, Applicants submit that the specification is proper and request entry of the same.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

Vincent K. Shier, Ph.D.
Registration No. 50,552

22850
Tel.: 703-413-3000
Fax: 703-413-3220
NFO:VKS